GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2210
ANSWERED ON:05.03.2003
BIG-EQUIVALENCE STUDIES ON MEDICINES
P.R. KHUTE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether any permission from DCGI is required to conduct Bio-equivalence studies on medicines for exports;

(b) if so, the details thereof;

(c) whether it is equally applicable for the new drugs which have been permitted in the country and are not yet approved for marketing in the country; and

(d) if so, the guidelines for conducting such bio-equivalence studies?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) to (c) Requirement of Bioequivalence study on medicine for export depends upon the requirements of an importing country, and it is not insisted upon by the office of the DCG(I).

(d) Bioequivalence studies are conducted as per accepted scientific norms. However, draft guidelines for conducting Bioequivalence studies in the country are also being prepared.